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Are self-reported telemonitored blood pressure readings affected by end-digit preference: a prospective cohort study in Scotland

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ABSTRACT

Objective Simple forms of blood pressure (BP) telemonitoring require patients to text readings to central servers creating an opportunity for both entry error and manipulation. We wished to determine if there was an apparent preference for particular end digits and entries which were just below target BPs which might suggest evidence of data manipulation.

Design Prospective cohort study

Setting 37 socioeconomically diverse primary care practices from South East Scotland.

Participants Patients were recruited with hypertension to a telemonitoring service in which patients submitted home BP readings by manually transcribing the measurements into text messages for transmission ('patient-texted system'). These readings were compared with those from primary care patients with uncontrolled hypertension using a system in which readings were automatically transmitted, eliminating the possibility of manipulation of values ('automatic-transmission system').

Methods A generalised estimating equations method was used to compare BP readings between the patient-texted and automatic-transmission systems, while taking into account clustering of readings within patients.

Results A total of 44 150 BP readings were analysed on 1068 patients using the patient-texted system compared with 20 705 readings on 199 patients using the automatic-transmission system. Compared with the automatic-transmission data, the patient-texted data showed a significantly higher proportion of occurrences of both systolic and diastolic BP having a zero end digit (OR 2.1, 95% CI 1.7 to 2.6) although incidence was <2% of readings. Similarly, there was a preference for systolic 134 and diastolic 84 (the threshold for alerts was 135/85) (134 systolic BP OR 1.5, 95% CI 1.3 to 1.8; 84 diastolic BP OR 1.5, 95% CI 1.3 to 1.9).

Conclusion End-digit preference for zero numbers and specific-value preference for readings just below the alert threshold exist among patients in self-reporting their BP using telemonitoring. However, the proportion of readings affected is small and unlikely to be clinically important.

Trial registration number ISRCTN72614272; Post-results.

Strengths and limitations of this study

- This study involved the analysis of a very large sample size of over 44 000 patient-texted blood pressure (BP) readings recorded by 1068 patients.
- We compared with a cohort of 20 705 automatically transmitted telemonitored BP readings recorded by 199 patients for which there was no possibility of manipulation of readings.
- Because of differential recruitment criteria, the 'automatic-transmission' cohort had higher BP readings than the 'patient-texted' cohort although this was addressed to some extent in the statistical analysis.

INTRODUCTION

Hypertension is one of the most important risk factors for stroke and heart disease, and is estimated to contribute to 7.6 million premature deaths each year worldwide.[1] Although antihypertensive medication is highly effective, control of blood pressure (BP) is often poor in routine clinical practice.[2] Reasons for poor BP control include irregular monitoring,[3] reluctance of physicians to intensify medications[4] and poor adherence to medication by patients.[5]

BP varies considerably over time, so infrequent measurements as part of routine clinical reviews are often poor indicators of response to therapy.[6] Furthermore, clinic BP measurements have poor test–retest reliability compared with daytime ambulatory BP monitoring or multiple measurements taken at home,[7] and are less predictive of mortality or cardiovascular outcomes.[8–10]

Telemonitoring of hypertension involves patients submitting home BP readings directly to their clinician using the internet or other technology, with the data being used to assist with diagnosis or ongoing management. A recent meta-analysis of randomised

controlled trials concluded that telemonitoring results in a clinically significant reduction in systolic and diastolic BP.[11] This has also been shown more generally with respect to self-monitoring of BP in hypertensive patients, when accompanied with co-interventions involving additional support, which is based on the results from an individual patient data meta-analysis.[12]

A low-cost telemonitoring BP service is currently being rolled out in primary care in NHS Lothian in Scotland. The telemonitoring platform used in this study involves patients checking their BP at home with a frequency determined by their general practitioner according to the clinical context. For example, some patients took daily readings, some twice weekly and others monthly. The patients had to transcribe the readings into text messages to send to the system which generated summary reports for their practice at one to three monthly intervals. If readings were above clinically determined BP thresholds, then this would trigger an alert from the system. Different thresholds and recommended actions were used depending on the patient's condition as per guidelines in place at the time. For people with diabetes or chronic kidney disease (CKD), the threshold for alerts was typically set at 125/75, whereas for most other patients it was 135/85.

The manual transcribing of measurements required by this system contrasts with a system previously used in a trial in Lothian in which Bluetooth-connected sphygmomanometers automatically transmitted data so that there was no possibility of transcribing errors or value manipulation.[13] There were concerns with the new patient-texted system that patients might provide inaccurate readings.

Many studies have shown a tendency for nurses and physicians throughout the world to record BP readings to the nearest zero ('end-digit preference').[14–25] Indeed, in a recent meta-analysis published in 2017,[26] as many as 34 studies were identified that reported over-representation of zero end digits in BP readings by as much as 71%.[20 26] In part, this is due to historical sphygmomanometers requiring manual estimation of BP, and the phenomenon is reduced (but not eliminated) with automatic digital monitors.[14] In addition, there is a tendency for readings taken by professionals to cluster just below treatment threshold values. This has been investigated in a few studies,[14 17 24 25] but results are inconsistent, and the clinical impact is unclear.

To our knowledge, no studies to date have examined end-digit preference of BP readings measured and texted by patients. The SMART study considered end-digit preference in self-reported BP measurements recorded by patients at home, although this was not in the context of a telemonitoring system.[27] Steventon *et al*[28] found evidence of end-digit preference in weight measures among patients with heart failure using telemonitoring. However, neither study had a comparator group using automatically transmitted data in which there was no possibility of data manipulation.

Our hypothesis was that if a proportion of patients are estimating or manipulating the BP values that they submit to the system, then there would also be a preference for zero end digits. We were also interested in whether there was a specific-value preference where patients were preferentially recording BP readings just below the BP thresholds in order to avoid triggering an alert.

We therefore aimed to investigate the occurrence of end-digit bias and specific-value preference in BP readings taken using the patient-texted telemonitoring system by comparison with readings from the automatic-transmission system.

METHODS AND ANALYSIS

There were two cohorts of patients included in the study: one from a telemonitoring service rollout involving a patient-texted telemonitoring system and one from a, previously published, randomised controlled trial using an automated telemonitoring system.[13] Further details of each of these cohorts are given below.

Scale-up BP: a system using 'patient-texted' BP readings

Thirty-seven family practices volunteered to use a text-based telemonitoring system as an option for routine care in the 'Scale-up BP' initiative in NHS Lothian, Scotland. Data were collected from all patients recruited to the telemonitoring system from the 37 practices between 2 September 2015 and 30 June 2017.

Health professionals within each practice identified patients with hypertension who normally attended the primary care practice for BP monitoring. Patients were eligible to use the text-based telemonitoring system (Florence, https://www.getflorence.co.uk/) if they were named on the practice hypertension register, had newly diagnosed hypertension or their BP control needed careful management to optimise use of antihypertensive medication.

Eligible patients were either given a leaflet during a routine appointment or sent a letter from the practice nurse or doctor outlining the telemonitoring approach to managing BP. They were asked to bring their mobile phone (if they had one) to their next appointment. If the patient (or a member of their family) were able and willing to use the telemonitoring system, they were given an Omron sphygmomanometer[29] with an appropriate sized cuff, and the text-based telemonitoring system was demonstrated. The system was set to deliver a text reminder to measure BP at a frequency determined by the patient's clinician according to the clinical context. After training, patients were asked to demonstrate their ability to take their BP and respond to the text prompts. The general practitioner (GP) or practice nurse reviewed a summary of BPs sent to the practice at least three monthly and contacted patients if there were any problems. The patients were informed that the system was not monitored on a daily basis, and very high BPs, changes in readings or any problems with their medication should be reported in the usual way. Patients undertaking telemonitoring were asked to consent to their data to be used for evaluation of the system. The Scale-up BP study was considered by the

Table 1 Descriptive statistics for systolic and diastolic blood pressure (BP) in the patient-texted and automatic-transmission systems

	Patient-texted systolic BP	Automatic-transmission systolic BP	Patient-texted diastolic BP	Automatic-transmission diastolic BP
N	44 150	20 705	44 150	20 705
Mean	131.87	141.74	79.73	85.36
SD	14.87	15.07	9.96	12.27
Median	131	141	80	85
Mode	134	144	80	86
IQR	123 to 140	131 to 150	73 to 85	78 to 93
Min	70	75	40	30
Max	225	224	124	135

local ethics scientific officer to be service evaluation and thus not to require ethical approval.

Data were obtained in monthly spreadsheets from a secure online web page. The spreadsheets were stripped of patient identifiers and did not include any sociodemographic data which meant that it was impossible to identify individual patients. After receiving the data, the following criteria were applied to exclude any highly improbable BP readings or clear input errors:

- systolic value below 60 mm Hg or above 262 mm Hg
- diastolic value below 40 mm Hg or above 124 mm Hg
- systolic lower than diastolic value
- systolic value less than 10 mm Hg higher than diastolic value
- missing systolic or diastolic values.

Health Impact of nurse-led Telemetry Services trial: a system using 'automatically-transmitted' BP readings

As a comparator, we used BP data collected during the Health Impact of nurse-led Telemetry Services (HITS) trial,[13] a multicentre randomised controlled trial in 20 primary care practices in the same health board as for the Scale-up BP study. A total of 401 people aged 29–95 years with uncontrolled BP (mean daytime ambulatory BP ≥135/85 mm Hg but ≤210/135 mm Hg) were recruited. The trial methods and results are reported in detail elsewhere.[13] The patients used a validated sphygmomanometer (Stabil-O-Graph)[30] linked by a short range wireless connection to a mobile phone, which automatically transmitted readings to a central server, such that it was not possible to manipulate the value of the BP readings.

For the HITS trial,[13]patients were recruited between February 2009 and October 2010. Patients were eligible if their last recorded clinic BP was over 145 mm Hg systolic or 85 mm Hg diastolic and they were on their practice hypertension register. They subsequently underwent daytime ambulatory BP monitoring to exclude those with 'white coat' hypertension. Exclusion criteria were secondary hypertension, hypertension or renal disease managed in secondary care, atrial fibrillation, diabetes, pregnancy, stroke, treatment for cardiac event or other life-threatening illness within the past 6 months or surgery within the last 3 months, under 18 years and inability to use self-monitoring equipment. Patients received automatic feedback from the system informing them that their BP was controlled (<135/85), not yet controlled but improving, or that it was uncontrolled and that they should contact their clinician. Only anonymised BP readings from the telemonitoring system arm of the trial were made available for this analysis. The target for the HITS trial was the same as Scale-Up BP (135/85) although there were no participants with lower targets. The practice nurse monitored the readings as in Scale-up BP.

Written informed consent was obtained from participants in both studies.

Analysis methods

Overall descriptive statistics were calculated for the patient-texted and automatic-transmission BP readings. An independent samples t-test was used to compare mean systolic and diastolic BP between cohorts after first aggregating the data to the patient level and calculating a mean value per patient. The prevalence of specific values of systolic and diastolic BP readings was compared between the two data transmission cohorts. We then examined the percentage occurrence of all possible end digits (from 0 to 9), comparing between cohorts using clustered bar charts for systolic and diastolic BP. A cross tabulation of the end digits for systolic and diastolic within each dataset allowed to us to examine for the possibility of 'double zero' end-digit preference, where 'double zero' means that both systolic and diastolic BP have a zero end digit.

We used generalised estimating equations (GEE) analysis to directly compare between patient-texted/automatic-transmission data while taking into account clustering of observations by patients. To assess zero end-digit preference, binomial GEE models were fitted to the outcomes: double zero end digits, zero systolic end digit and zero diastolic end digit.

To assess specific-value preference of values, we were interested in systolic and diastolic values just below the hypertension threshold in both studies for alerts of 135/85. Therefore, we fitted binomial GEE models to the specific-value outcomes of systolic 134 and diastolic

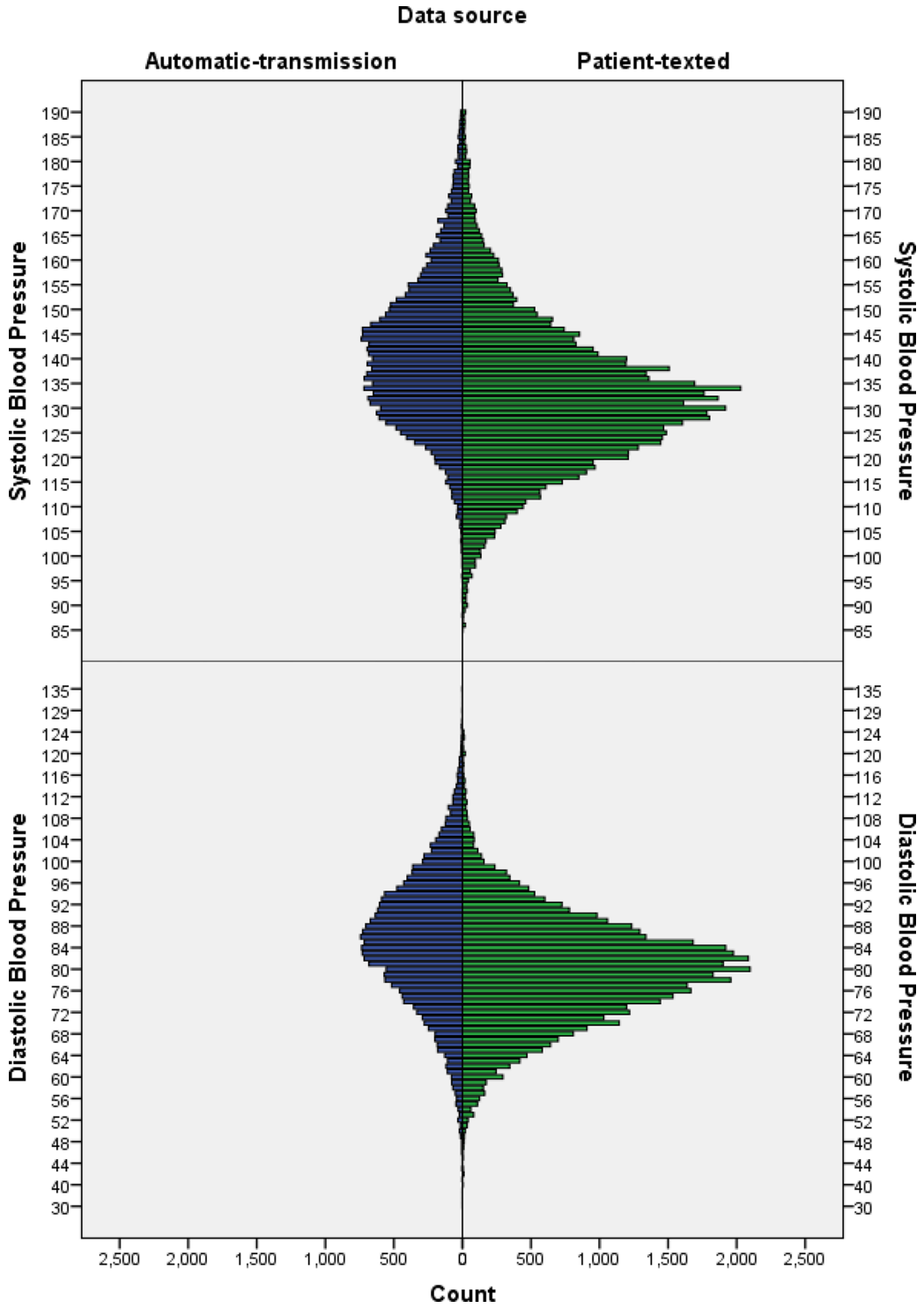

Figure 1 Population pyramids of the raw systolic blood pressure readings (in the range of 85–190) and diastolic readings (in the range of 30–135) in the patient-texted and automatic-transmission systems.

84. Unlike for other BP thresholds (eg, 120/80), these values are not confounded by double-zero preference. This analysis excluded patients from the patient-texted cohort using personalised limits other than the standard threshold for alerts (ie, 135/85). To address confounding due to population-level differences in the level of BP control, we also confined the samples in both groups to only include patients with median BPs in a restricted range (130–138 for systolic, and 82–86 for diastolic). This was to make the patient samples as similar as possible in terms of level of BP control.

In sensitivity analysis, we performed the same analysis as above, but restricting the subgroup of patients to those submitting at least 50 readings. This allowed us to investigate if end-digit preference was present even among highly engaged individuals.

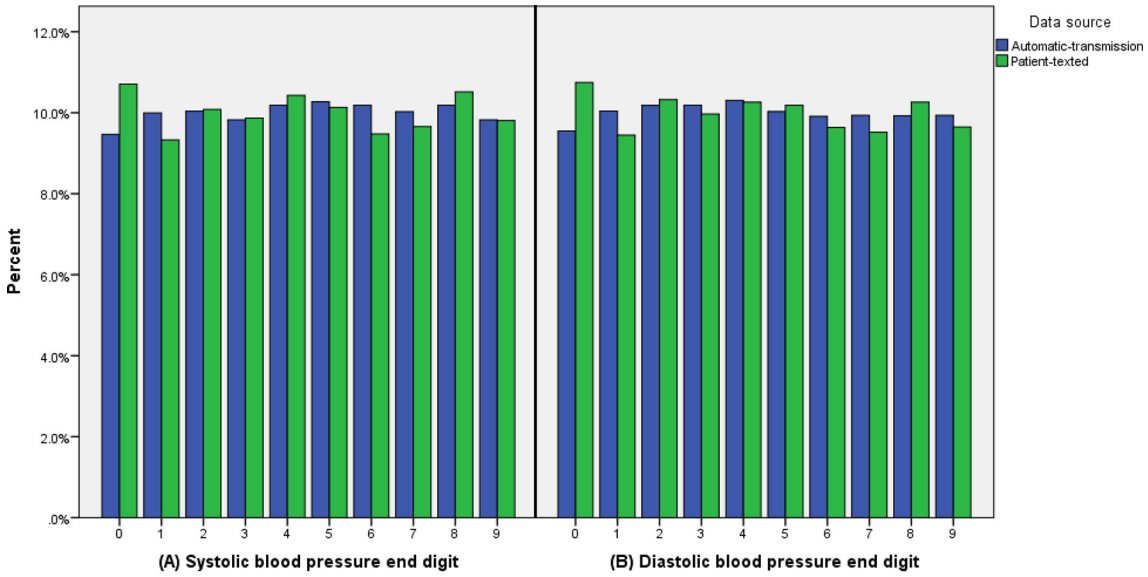

Figure 2 Clustered bar charts for the systolic (A) and diastolic (B) end digits in the patient-texted and automatic-transmission systems.

All GEE models assumed an exchangeable correlation structure. Analysis was by 'complete cases' only, and so incomplete BP readings were excluded.

The 'gee' package[31] in R software[32] was used for the GEE analysis. All other statistical analyses and graphs were produced using SPSS software V.21.[33]

RESULTS

A total of 44 269 BP readings were taken by 1069 patients using the patient-texted system. There were no missing systolic readings. Seventy-one readings were excluded because the diastolic value was missing. The following readings were excluded because they were implausible. Sixty-one systolic readings were below 60 mm Hg, 17 systolic readings were above 262 mm Hg, 17 diastolic readings were below 40 mm Hg, 11 diastolic readings were above 124 mm Hg, 12 readings had systolic BP lower than diastolic and a further 8 readings had systolic value within 10 mm Hg of the diastolic value. After applying these exclusion criteria, we had a final cleaned dataset consisting of 44 150 readings from 1068 patients.

The automatic-transmission data consisted of 20 705 readings on 199 patients. There was a median of 18 readings per patient for the patient-texted data (IQR 8–41, range 1–786 readings), compared with a median of 80 readings per patient for the automatic-transmission data (IQR 59–124, range 1–559 readings). A total of 211 patients took over 50 readings in the patient-texted data (20%) compared with 171 patients in the automatic transmission (86%). Patients in the patient-texted group used the system for a median of 22 weeks (range 0–93 weeks) compared with a median of 26 weeks (range 0–42 weeks) for those in the automatic-transmission system group.

Analysis of raw BP values

Descriptive statistics for the patient-texted BP readings compared with the automatic-transmission readings are shown in table 1.

Reflecting the different eligibility criteria, the patient-texted cohort had mean systolic and diastolic values that were significantly lower than in the automatic-transmission cohort (t-test P<0.001 for both).

Population pyramids of the systolic and diastolic BP data are shown in figure 1.

In the patient-texted cohort, the highest percentage frequencies were observed for systolic BPs in the range of 127–135 (2.9% or above), and the most frequently observed was a value of systolic 134 (1623 occurrences, 3.7%). Systolic 134 was also one of the most frequently observed systolic values in the automatic-transmission cohort, although the percentage occurrence was only 2.8%.

For diastolic BPs in the patient-texted cohort, the highest percentage frequencies were observed for readings in the range of 78–84 (all above 4%), with the most frequently observed diastolic value being 80 (4.8%). In contrast, the percentage occurrence of 80 was only 2.7% in the automatic-transmission cohort, whereas the most frequent diastolic value had a percentage of 3.6% (86).

Analysis of BP end digits

Figure 2 shows clustered bar charts for the systolic and diastolic BP end digits, respectively.

The most notable difference between the two datasets regarding end-digit frequencies was for the zero end digit, indicating possible zero end-digit preference for both systolic and diastolic BP. In the patient-texted dataset, 4727 zero end digits were observed for systolic

Table 2 Cross tabulation of systolic and diastolic end-digit readings for patient-texted and automatic-transmission datasets, with results shown as percentages of the total number of readings

Data source			Diastolic blood pressure end digit (%)										
			0	1	2	3	4	5	6	7	8	9	Total (%)
Automatic-transmission system	Systolic blood pressure end digit	0	0.9	1.0	1.0	0.9	0.9	0.9	1.0	1.0	1.0	0.9	9.5
		1	1.0	1.0	0.9	1.0	1.0	1.0	1.0	0.9	1.0	1.0	10.0
		2	0.9	1.1	0.9	1.0	1.0	1.0	1.0	1.0	1.0	1.0	10.0
		3	1.0	1.0	1.0	1.0	1.0	1.0	0.9	1.0	1.0	0.9	9.8
		4	1.0	1.1	1.2	1.0	1.1	0.9	1.0	1.1	0.9	1.0	10.2
		5	1.0	1.0	1.0	1.0	1.2	1.0	1.0	1.1	0.9	1.0	10.3
		6	1.0	1.0	1.1	1.0	0.9	1.0	1.0	1.0	1.1	1.1	10.2
		7	1.0	1.0	1.1	1.0	1.1	1.0	1.0	1.0	1.0	0.9	10.0
		8	1.0	1.0	1.0	1.1	1.1	1.1	1.0	1.0	0.9	1.0	10.2
		9	0.9	1.0	1.0	1.1	1.0	1.1	0.9	0.8	0.9	1.1	9.8
	Total		9.5	10.0	10.2	10.2	10.3	10.0	9.9	9.9	9.9	9.9	100.0
Patient-texted system	Systolic blood pressure end digit	0	1.7	1.0	1.0	1.0	0.9	1.2	0.9	1.0	1.0	1.0	10.8
		1	1.0	1.1	1.0	1.0	1.0	1.0	0.8	1.0	0.8	0.8	9.4
		2	1.0	1.1	1.2	1.0	1.0	0.9	1.0	0.9	1.0	1.0	10.2
		3	1.0	0.9	0.9	1.0	1.1	0.9	1.0	1.0	1.0	0.9	9.7
		4	1.0	0.9	1.0	1.0	1.3	1.0	1.0	0.9	1.2	1.0	10.4
		5	1.1	0.9	1.0	0.9	1.0	1.3	0.9	1.0	1.1	1.0	10.1
		6	0.9	0.8	1.0	1.0	1.0	0.9	1.0	0.9	0.9	0.9	9.3
		7	0.9	0.9	0.9	1.0	0.9	1.0	1.1	1.1	0.9	1.0	9.7
		8	1.1	1.1	1.0	1.1	1.0	1.0	1.0	1.0	1.3	1.0	10.5
		9	1.0	0.9	1.0	1.0	1.0	1.0	1.0	0.9	0.9	1.2	9.9
	Total		10.7	9.5	10.1	10.0	10.2	10.2	9.6	9.8	10.2	9.7	100.0

BP (10.7%) compared with 1960 (9.5%) in the automatic-transmission dataset. Similarly, for diastolic BP, 4744 zero end digits (10.7%) were observed in the patient-texted dataset compared with 1977 (9.5%) in the automatic-transmission dataset.

Table 2 shows a cross tabulation of the percentages of systolic and diastolic end digits for the patient-texted and automatic-transmission datasets, with percentages calculated out of the total number of BP readings.

Table 2 shows that 1.7% of the BP readings had a double-zero end digit, whereas the majority of the other end-digit combinations were in the range of 0.9%–1.2%. If the end digits were entirely random, then we would expect a percentage of about 1% in each cell, and unsurprisingly the automatic-transmission system is consistent with this supposition. Out of all patients with a diastolic reading ending in 0, 16% also had a systolic reading ending in 0 (and vice versa).

GEE analysis

The results from the GEE analysis are shown in table 3.

The odds of double zeros in the patient-texted population were approximately twice those in the automatic-transmission (OR 2.1, 95% CI 1.7 to 2.6). Our conclusions

Table 3 ORs for the comparison of patient-texted versus automatic-transmission from a generalised estimating equations model fitted to the repeated measures outcome data

Outcome	Automatic-transmission	Patient-texted	OR	95% CI of OR	Robust Z scores
Double zero	0.9% (177/20705)	1.7% (761/44150)	2.12	1.72 to 2.62	7.07
Systolic end digit of zero	9.5% (1960/20705)	10.7% (4727/44150)	1.15	1.08 to 1.22	4.53
Diastolic end digit of zero	9.5% (1977/20705)	10.7% (4744/44150)	1.17	1.10 to 1.25	4.72
Systolic 134*	4.1% (266/6478)	6.3% (979/15484)	1.52	1.28 to 1.82	4.70
Diastolic 84†	5.5% (299/5450)	8.8% (795/9083)	1.54	1.28 to 1.86	4.48

*Only includes patients using the standard protocol with median systolic blood pressure in the range of 130–138.
†Only includes patients using the standard protocol with median diastolic blood pressure in the range of 82– 86.

were unchanged when restricting the sample to highly engaged patients recording over 50 readings (OR 1.8, 95% CI 1.5 to 2.1, see online supplementary file 1), or when restricting both samples to have median BP above 120/80 (OR 1.9, 95% CI 1.6 to 2.4, see online supplementary file 2).

We also found evidence of specific-value preference for systolic 134 and diastolic 84 in patients following the standard protocol (see table 3), presumably due to the threshold for receiving alerts of 135/85 in the patient-texted system. Again, this conclusion remained unchanged after considering highly engaged patients recording 50 readings or above (see online supplementary file 1).

DISCUSSION

We found evidence of end-digit preference for 'zero' BP readings in the patient-texted population when compared with the automatic-transmission cohort. Zero end digits tended to occur together, suggesting that end-digit preference is often expressed for both diastolic and systolic readings simultaneously. This is consistent with the literature which shows strong evidence of zero end-digit preference among primary care professionals taking BP measurements. For example, Lyratzopoulos *et al*[22] examined the quality of measurements in routinely collected data, and did not find any evidence of digit preference for the final digits of height, weight or cholesterol measurements taken by health professionals, but did find a strong zero end-digit preference for systolic and diastolic BP measurements.

We also found evidence of specific-value preference below the hypertension threshold (in non-diabetics) of 135/85. This finding differs from some studies[17 24] which did not find specific-value preference near treatment thresholds. This may be because in our study, patients using the patient-texted system received automated messages when their readings breached the threshold. Specific-value selection of readings below the threshold may not always be due to inaccuracy or inappropriate rounding; anecdotally, some patients faced with a higher than expected BP will repeat the measurement until they achieve an acceptable reading.

Our results were unchanged after a sensitivity analysis restricting the data to those patients recording more than 50 readings. This suggests that high engagement and familiarity with a system does not eliminate end-digit preference or specific-value preference, and that value preference remains even when restricting the sample to those who are most enthusiastic and highly engaged with the study. This finding is consistent with the results from the EffetS d'une intervention multifaCtorielle sur les fActeurs de risque des patients hyPErtendus(ESCAPE) cluster randomised controlled trial[18] which suggest that end-digit preference does not diminish, and may actually increase over time as patients become more familiar with the use of electronic devices, and aware of thresholds.[18]

Nevertheless, despite the statistically significant results, they are unlikely to be clinically relevant: in the patient-texted group, the overall percentage of double-zero readings was still below 2%, and occurrences of specific-value selection of systolic 134 and diastolic 84 were still within 4% of the automated system. However, it has been suggested that even very small differences could affect patient care.[16 19 23] Hence, it may be important to inform patients before using the telemonitoring system that accuracy of readings is important, and then the onus will be on the patient to provide accurate readings to ensure appropriate care.

A strength of our study is the very large sample size of almost 65 000 BP readings across 1267 patients in total; therefore, we were well powered to detect potential end-digit preference. Patients were recruited from routine practice so should be representative of the patients who would participate in a telemonitoring service, although recruitment only took place in Scotland and so the results may not be generalisable to patients in other countries. Another advantage of our study was that we were able to compare with individual level data from a cohort of patients taking their readings at home but with no possibility of data manipulation. Most studies in the literature do not have a suitable comparison group and therefore have to rely on methods to detect end-digit preference within single samples. However, because of differences in the eligibility criteria, our patient populations had significantly different levels of BP control making comparison challenging, especially for the analysis of specific-value preference. In particular, patients with CKD (stages 3–5) or who had diabetes were included in the patient-texted cohort but were excluded from the automatic-transmission cohort. This made it difficult to establish specific-value preference below the BP thresholds since any such apparent 'preference' may be confounded with the observed differences between populations. However, our GEE analysis attempted to address this by confining the samples in both groups to only include patients with median BPs within a restricted range and using a standard protocol (ie, excluding patients with CKD and diabetes). For the end-digit preference analysis more generally, in sensitivity analysis we restricted the samples to patients with median BP above 120/80 and our conclusions were unchanged.

In conclusion, our results provide evidence for the existence of zero end-digit preference and specific-value preference among patients self-reporting their BP using telemonitoring. However, the proportion of readings affected by this is small and unlikely to be clinically important. The extent of end-digit preference is not so great as to warrant the use of more expensive systems that allow the automatic transfer of BP readings, and so telemonitoring services can continue to use manual entry systems. However, we recommend that

patients are reminded to record readings as accurately as possible to achieve appropriate care.

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Contributors BM, PP, HP, JH and AS made substantial contributions to the conception and design of the work. MP and VSH monitored the implementation of the telemonitoring system and co-ordinated the study. MP acquired the raw data. RAP planned and performed the statistical analysis. RAP wrote the first draft of the paper. All authors revised and commented on the manuscript.

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Competing interests None declared.

Patient consent Obtained.

Ethics approval The HITS trial had ethical approval from the South East Scotland Research Ethics Committee (reference number 08/S1101/38).

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement The dataset used in this study is available for download from figshare, DOI: 10.6084/m9.figshare.5363428

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